UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE FLINT WATER LITIGATION	Case No. 5:16-cv-10444-JEL-MKM Hon. Judith E. Levy
This Document Relates To: *Gaddy et al. v. Flint et al.* *Meeks et al. v. Flint et al.*	Case No. 5:17-cv-11166-JEL-MKM Case No. 5:17-cv-11165-JEL-MKM

DEFENDANTS VEOLIA NORTH AMERICA, LLC, VEOLIA NORTH AMERICA, INC., AND VEOLIA WATER NORTH AMERICA OPERATING SERVICES, LLC'S OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* TO PRECLUDE EVIDENCE REGARDING THE EXPERIMENTAL NATURE, UNUSEFULNESS, LACK OF AUTHORIZATION, AND ILLEGALITY OF DR. AARON SPECHT'S PXRF TESTING

STATEMENT OF ISSUES PRESENTED

1. Is evidence regarding the experimental nature, unusefulness, lack of authorization, and illegality of Dr. Aaron Specht's pXRF testing relevant to the reliability and accuracy of his pXRF device and his credibility as a witness?

   VNA answers: "Yes."

   Plaintiffs answer: "No."

2. Is evidence regarding the experimental nature, unusefulness, lack of authorization, and illegality of Dr. Aaron Specht's pXRF testing admissible because it is not substantially more prejudicial than probative?

   VNA answers: "Yes."

   Plaintiffs answer: "No."

CONTROLLING OR MOST APPROPRIATE AUTHORITIES

United States v. Arnott, 704 F.2d 322 (6th Cir. 1983)

Fed. R. Evid. 402

Fed. R. Evid. 403

Fed. R. Evid. 611

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INTRODUCTION

Dr. Aaron Specht measured lead in Plaintiffs' tibias using portable x-ray fluorescence (pXRF) devices. The devices were manufactured for industrial use but modified by Dr. Specht for use on humans. The devices are not approved for use in clinical settings and have never been validated for use on children in any academic research.

The Court allowed Dr. Specht to testify under *Daubert* and Rule 702 based on his recent modifications to the pXRF testing, where he attempted to address problems with using the device on children. Opinion & Order on Mot. to Exclude Specht (Specht Op.) 4-6, ECF No. 447, PageID.35605-35607. The Court concluded that VNA's "concerns about Dr. Specht's methodology and conclusions are not without merit," but "are more appropriately weighed by a jury." *Id.* at 8, PageID.35609. Plaintiffs themselves had argued that VNA's challenges were "more appropriate for cross-examination" as opposed to warranting exclusion under *Daubert*. Pls. Response to VNA Mot. to Exclude Specht (Pls. Specht Response) 2, ECF No. 368, PageID.23328.

Plaintiffs now seek to limit VNA's ability to cross-examine Dr. Specht or otherwise challenge his opinions. Plaintiffs concede that VNA can challenge the reliability of pXRF testing but seek to preclude evidence regarding safety concerns about the pXRF device and the experimental nature, unusefulness, lack of

authorization, and illegality of Dr. Specht's pXRF testing. Br. in Supp. of Pls. Mot. to Exclude Evidence Regarding pXRF Testing (Pls. Br.) 4 & n.1, ECF No. 514, PageID.39379. With respect to this type of evidence—about safety—the Court should not rule on the motion now, but should wait to see if Plaintiffs open the door at trial to arguments about whether the pXRF device is harmful to human health. The remaining evidence that Plaintiffs seek to preclude is highly relevant to the novelty, reliability, and usefulness of pXRF testing and Dr. Specht's credibility.

First, testimony from VNA's experts and public statements from prominent Flint pediatricians that pXRF testing is experimental, is not approved for use in clinical settings, and serves no medical purpose plainly are relevant. Plaintiffs intend to portray Dr. Specht's pXRF testing as a scientific and accepted technology for identifying "lead poisoning." Pls. Br. 5, PageID.39380. VNA is entitled to dispute that by demonstrating that the use of pXRF to measure bone lead in living persons has been limited to academic research settings and serves no clinical purpose. That is particularly true for children, as Dr. Specht's own research has demonstrated. The Court found that VNA's *Daubert* challenges went to weight, not admissibility. The Court should reject Plaintiffs' attempt to now limit VNA's ability to challenge the weight that the jury should afford Dr. Specht's pXRF testing.

Second, evidence from Thermo Fisher—the manufacturer of the pXRF device—also is relevant to the experimental nature of pXRF testing and to Dr. Specht's credibility. Dr. Specht obtained the pXRF devices used in Flint under false pretenses, and when Thermo Fisher found out, it instructed him to stop using the devices outside of academic research approved by an institutional review board (IRB). Dr. Specht's employer, Harvard, has disclaimed any involvement in, and has not approved, his litigation work in Flint. Notably, Thermo Fisher had taken the same position concerning the use of its pXRF devices even before objectors to the settlement raised concerns about the safety of the pXRF.

Third, Dr. Specht violated Michigan law by performing pXRF testing on Plaintiffs before registering his devices with the State of Michigan and without proper health and safety protocols in place. While the Michigan Occupational Safety & Health Administration (MIOSHA) opted not to impose civil or criminal penalties for the violations, it did require Dr. Specht and Plaintiffs' counsel to take corrective actions. Dr. Specht's failure to comply with Michigan law is relevant to his credibility and to the unscientific nature of his testing procedures.

Plaintiffs have not identified any basis for precluding evidence on the experimental nature, unusefulness, lack of authorization, and illegality of Dr. Specht's pXRF testing under either Rule 402 or Rule 403. If Plaintiffs are concerned that jurors might be confused into believing that they must decide

whether Dr. Specht's pXRF testing is harmful to human health, that issue easily could be addressed through jury instructions, if necessary.

BACKGROUND

To VNA's knowledge, this case marks the first time that pXRF testing has been used to diagnose individuals as "lead poisoned"—either for medical treatment in a clinical setting or to seek compensation for injuries in court.[1] The pXRF devices are manufactured and marketed by Thermo Fisher for industrial purposes. Since 2014, Dr. Specht has attempted to validate the use of a modified pXRF device to measure bone lead in humans, including children, in academic research settings.

To date, Dr. Specht's academic research has failed to validate the use of pXRF on children. In a 2016 paper, Dr. Specht found that pXRF did not produce accurate results in children and that "further investigation" was required "before [pXRF is] used further in pediatric populations." Ex. 2, A. Specht et al., *XRF-Measured Bone Lead (Pb) as a Biomarker for Pb Exposure and Toxicity Among Children Diagnosed with Pb Poisoning*, 21 Biomarkers 347, 351 (2016). In a 2019 paper, Dr. Specht again found that pXRF is "still being validated" for use on

[1] VNA is aware of only one prior instance in which a party sought to use bone lead testing evidence in court; the court excluded it. *See Dombroski v. Gould Elecs., Inc.*, 31 F. Supp. 2d 436, 442-43 (M.D. Pa. 1998) (using KXRF technology).

children and that "further work needs to be done" to understand the "new measurement system." *See* Ex. 3, A. Specht et al., *Childhood Lead Biokinetics and Associations with Age Among a Group of Lead Poisoned Children in China*, 29 J. Expo. Sci. Env't Epidemiol. 416, 416, 422 (2019). Although Dr. Specht claims to have resolved these problems through recent modifications to his pXRF testing methodology, Specht Op. 5, PageID.35606, he has not published any further academic research to validate the use of pXRF on children.

VNA moved to exclude Dr. Specht's pXRF testing under *Daubert* and Rule 702. In response, Plaintiffs repeatedly asserted that VNA's challenges were "more appropriate for cross-examination." Pls. Specht Response 2, PageID.23328; *see id.* at 17, PageID.23343 ("While VNA may have identified potential subjects of cross-examination, the authority [VNA] cites . . . does not justify wholesale exclusion."); *id.* at 19, PageID.23345 ("'Vigorous cross-examination, presentation of contrary evidence, and careful instruction . . . are the traditional and appropriate means of attacking shaky but admissible evidence.'" (quoting *Daubert v. Merrill Dow Pharms.*, 509 U.S. 579, 596 (1993))); *id.* at 20, PageID.23346 ("Exclusion of Dr. Specht's testimony is manifestly improper and any further testing of his methodology and opinions is best suited for cross-examination and careful instruction of the jury by the Court.").

The Court agreed with Plaintiffs that VNA's challenges to pXRF testing are "more appropriately weighed by a jury." Specht Op. 8, PageID.35609. As the Court explained, "[e]ven if Defendants are right that Dr. Specht's findings are inaccurate or prone to error, the remedy is to mount an effective defense at trial." *Id.* at 18, PageID.35619. "[T]he trial is the appropriate place for such arguments, and a jury the appropriate audience." *Id.*

LEGAL STANDARD

Relevant evidence is generally admissible. Fed. R. Evid. 402. Evidence is relevant if "it has any tendency to make a fact more or less probable than it would be without the evidence" and "the fact is of consequence in determining the action." Fed. R. Evid. 401. Courts may exclude relevant evidence only if "its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403.

Cross-examination may address "the subject matter of the direct examination and matters affecting the witness's credibility." Fed. R. Evid. 611; *see United States v. Arnott*, 704 F.2d 322, 324 (6th Cir. 1983) ("The subject matter of direct examination and issues of credibility are always open to cross-examination."); Fed. R. Evid. 607 ("Any party . . . may attack the witness's credibility").

ARGUMENT

I. Evidence That Dr. Specht's pXRF Testing Is Experimental, Not Useful, Not Authorized, And Illegally Performed Is Highly Relevant

A. Testimony From VNA's Experts And Public Statements Of Prominent Flint Pediatricians On These Topics Are Relevant

VNA does not intend to introduce evidence that Dr. Specht's pXRF testing is potentially harmful to human health unless Plaintiffs open the door to that issue.[2] However, evidence that pXRF testing is experimental, is not approved for use in clinical settings, and serves no medical purpose is relevant to the weight the jury should afford the test results. VNA intends to address these issues through its experts, Dr. Brent Finley and Dr. John Gaitanis, and by cross-examining Dr. Specht about public statements made by prominent Flint pediatricians who were involved in the Flint water crisis, Dr. Mona Hanna-Attisha and Dr. Lawrence A. Reynolds.

Plaintiffs concede that VNA's experts have provided admissible opinions on these topics. Plaintiffs concede that Dr. Finley addresses "the accuracy and reliability of pXRF testing." Pls. Br. 8, PageID.39383. Similarly, Plaintiffs concede that Dr. Gaitanis opines that pXRF has not been "'properly vetted for use

[2] In particular, VNA does not intend to introduce evidence about the level of radiation exposure from Dr. Specht's pXRF testing, and its experts do not intend to testify that the radiation exposure (or any other aspect of Dr. Specht's pXRF testing) is potentially harmful to human health.

in humans'" and "'has no role in medical practice'" and is not offering "a separate argument that it isn't safe." *Id.* (quoting Dr. Gaitanis's reports).

Dr. Hanna-Attisha and Dr. Reynolds also have made public statements questioning Dr. Specht's pXRF testing. Both are pediatricians in Flint and both have intimate knowledge of the Flint water crisis. Dr. Hanna-Attisha was one of the first people to raise concerns over lead exposure. Indeed, Plaintiffs' experts rely on Dr. Hanna-Attisha's work. *See, e.g.*, Michaels Report 10, 107-08, 133, ECF No. 330-15. Dr. Hanna-Attisha spoke out against Dr. Specht's pXRF testing, describing it as an instance "where something is being applied on them that is not tested, that has not been approved." Ron Fonger, *Flint Pediatrician Who Blew the Whistle on Water Crisis Won't Recommend Bone Scans for Kids*, Mlive (Mar. 15, 2021) (Fonger, *Flint Pediatrician*), https://bit.ly/3nJkLk8. She further explained that "[h]owever minimal the risk," "there is no benefit" from the testing because bone scans provide no information about where the lead came from or when. *Id.*[3]

Dr. Reynolds voiced similar concerns. Dr. Reynolds has been a pediatrician in Flint for many decades and served on the Flint Water Advisory Task Force. *See* Objections of Dr. Lawrence A. Reynolds, M.D., FAAP 2-3, No. 16-cv-10444 ECF No. 1436, PageID.55022-55023. Dr. Reynolds explained (accurately) that Dr.

[3] Dr. Hanna-Attisha also said that the testing was "another example of [] injustice." Fonger, *Flint Pediatrician*. VNA does not intend to use this statement at trial.

Specht's pXRF testing is not "part of an approved diagnostic procedure"; is not "a proven beneficial treatment protocol, especially for children"; and is not "an approved practice by any global regulatory agency or professional body." *Id*. at 6, PageID.55026. He further explained (again, accurately) that Dr. Specht's "[u]se of this unapproved industrial device to perform a bone scan . . . is at best[] unauthorized research." *Id*.[4]

VNA intends to cross-examine Dr. Specht about Dr. Hanna-Attisha's and Dr. Reynolds's public statements, which are relevant to the weight the jury should afford the pXRF test results. There is no basis to preclude that cross-examination. It will not confuse the jury or waste time. And Dr. Specht will have the opportunity to respond to Dr. Hanna-Attisha's and Dr. Reynold's criticisms of the experimental nature and lack of utility of his pXRF testing.

Plaintiffs argue that the Court found Dr. Hanna-Attisha's and Dr. Reynolds's comments "plainly irrelevant" to the *Daubert* "general acceptance" factor because they are not part of Dr. Specht's "scientific community." Specht Op. 17 n.2, PageID.35618. At trial, however, VNA is not limited to presenting evidence on *Daubert* factors. It is allowed to challenge the weight that the jury should afford pXRF test results. As Flint pediatricians who were at the center of the Flint water

[4] Dr. Reynolds also called Dr. Specht's pXRF testing a "human rights violation" and compared it to the Tuskegee experiment. Pls. Br. 7 & n.4, PageID.39382. VNA does not intend to use these statements at trial.

crisis, Dr. Hanna-Attisha and Dr. Reynolds have personal knowledge that pXRF testing is experimental, is not approved for use in clinical settings, and serves no medical purpose. VNA should be allowed to ask Dr. Specht about their public statements questioning his work.

B. Dr. Specht's Interactions With Thermo Fisher Are Relevant

Plaintiffs also seek to preclude inquiry into Dr. Specht's interactions with Thermo Fisher, the manufacturer of the pXRF device. Pls. Br. 14, PageID.39389. Dr. Specht's interactions with Thermo Fisher are relevant to the experimental nature of pXRF testing, as well as to Dr. Specht's credibility.

VNA acknowledges that Thermo Fisher provided assistance to Dr. Specht in performing academic, IRB-approved research, and it is not seeking to create a "mini-trial" over a "decade" of interactions. Pls. Br. 14, Page ID.39389. Recently, however, Dr. Specht was not candid with Thermo Fisher about how he intended to use pXRF devices in Flint, and when Thermo Fisher found out, it directed Plaintiffs' counsel to stop using the pXRF devices without IRB oversight. Plaintiffs have not identified any basis for excluding Dr. Specht's interactions with Thermo Fisher related to this litigation, and they are relevant to assessing the pXRF test results.

In particular, when Dr. Specht helped Plaintiffs' counsel rent pXRF devices from Thermo Fisher, he told Thermo Fisher only that he had "some potential

collaborators who are interested in using the device short term for *environmental surveillance*." Ex. 4, TFS00154 (emphasis added). He did not disclose that his collaborators were lawyers who wanted to use the devices on their clients in an effort to help prove their cases, and his use of the term "environmental surveillance" does not convey the actual purpose he had in mind. When Thermo Fisher found out how the devices were actually being used, it responded:

> [W]e write to advise you that Thermo Fisher has never marketed the XL3t [pXRF device] for any *in vivo* diagnostic use (including, without limitation, any such use to measure bone lead levels in living persons), nor have we sought or obtained FDA approval for such use. While we are aware of a limited number of occasions on which we have supported academic research into the use of Thermo Fisher handheld XRF devices to measure bone lead, such research was, to our knowledge, approved by a university IRB in each instance. Your use of the XL3t does not appear to arise in the context of academic research, and we are not aware of any IRB approval for your activities.

Ex. 5, TFS00396. Thus, Thermo Fisher made clear that it did not approve using the pXRF device on children for litigation purposes.

In granting final approval of the settlement with the state defendants, the Court expressed the view that Thermo Fisher's letter was an attempt to protect itself from liability after the objectors raised safety concerns. Opinion & Order 107, No. 16-cv-10444 ECF No. 2008, PageID.69643. The Court made that statement in connection with the settlement-approval process. But as the Court observed in its order on the *Daubert* motion, whether "Dr. Specht's findings are

inaccurate or prone to error" are matters for the jury. Specht Op. 18, PageID.35619. So too are challenges to Dr. Specht's credibility. Accordingly, the jury should be allowed to assess the significance of the Thermo Fisher letter as it relates to those issues.

In any event, the Court's premise that Thermo Fisher changed its position as a result of the objections raised during the settlement-approval process is mistaken. Thermo Fisher took the same position *before* the settlement objections. In late 2019, Dr. Specht helped a collaborator obtain a pXRF device for testing on animals. Thermo Fisher responded that it did "not recommend using our analyzers to test on humans or animals" and that, if Dr. Specht and his collaborator wanted to make the purchase, they would have to get IRB approval and make other commitments. Ex. 6, HU005061. Dr. Specht responded that "[w]e always do this in the case of using the device and it is very important that we have the approvals from . . . any institutional review boards prior to doing this type of work." *Id.*

Thermo Fisher's letter to Plaintiffs' counsel in 2021 therefore was fully consistent with both its longstanding position that it would provide pXRF devices only for academic, IRB-approved research and Dr. Specht's past assurances that he would use the pXRF devices on living subjects only with IRB approval. Dr. Specht did not receive IRB approval for his litigation work in Flint; indeed, Harvard has disclaimed any involvement in Dr. Specht's work in Flint. *See, e.g.*,

Ex. 7, Ltr from Genevieve Aguilar, Harv. Univ., to David Rogers (May 28, 2021) ("[T]here are no human subjects research studies that the [Harvard] IRB has approved that involve the use of the pXRF as a radiation source at Harvard owned or controlled facilities"; "Harvard disagrees with any suggestion that the [Harvard] IRB or related-radiation safety committee at Harvard has approved the use of the pXRF as a radiation source for human subjects research at Harvard.").

The jury should be allowed to hear that the pXRF device manufacturer does not approve of how Dr. Specht used the device in this litigation. Dr. Specht's interactions with Thermo Fisher are relevant to the experimental nature of pXRF testing. They also are highly relevant to Dr. Specht's credibility, which will be a hotly contested issue at trial. Dr. Specht insists that alterations he made to the pXRF testing enabled him to take accurate measurements in children. But he has not provided VNA with the software that would enable it to check his work or subjected any pXRF testing on children to peer review; this case is the first time Dr. Specht has ever used his new methodology to measure bone lead in children. In denying VNA's motion to exclude Dr. Specht's opinions and measurements outright, the Court never suggested that VNA could not challenge Dr. Specht's credibility at trial. Evidence that Dr. Specht misled Thermo Fisher in order to acquire pXRF devices for use in developing evidence for trial bears directly on his credibility. If he deceived Thermo Fisher, it is more likely that he was not being

entirely candid about validating the device for use in children. Accordingly, for this reason as well, the evidence relating to Thermo Fisher is relevant and admissible.

C. Dr. Specht's Violations of Michigan Law Are Relevant

Plaintiffs' motion does not seek to preclude reference to Dr. Specht's violations of Michigan law. VNA addresses them here out of an abundance of caution to the extent they overlap with the "safety" issues raised in Plaintiffs' motion. Dr. Specht's failure to comply with MIOSHA rules in testing Plaintiffs is relevant both to his credibility and the unscientific nature of his testing procedures.

Dr. Specht violated Michigan law by measuring Plaintiffs' bone lead before registering the pXRF devices with the State *See* Mich. Admin. Code R. 333.5037. When MIOSHA found out about Dr. Specht's use of the pXRF device, it immediately raised concerns because "XRF machines are typically used to scan materials to determine the element content" and "[t]he current use of the XRF machines is a newer type of use." Ex. 8, MIOSHA, *General Activity Report* (Mar. 18, 2021). MIOSHA ultimately found that Dr. Specht and Plaintiffs' counsel had violated Michigan law by operating an unregistered radiation machine and doing so without proper safety protocols. Violations of this sort are punishable by "imprisonment for not more than 6 months, or a fine of not more than $200.00, or both." Mich. Comp. Laws § 333.2261. MIOSHA elected not to seek civil or

criminal penalties for the violations, but instead required Plaintiffs' counsel to take corrective action by putting proper safety protocols in place (long after Dr. Specht had already tested Plaintiffs). *See* Ex. 9, MIOSHA, *X-Ray Inspection Report* (May 4, 2021); Ex. 10, MIOSHA, *X-Ray Inspection Report* (June 25, 2021).

Plaintiffs' motion does not identify any basis to preclude inquiry into Dr. Specht's violations of MIOSHA rules in performing the pXRF testing at issue. VNA does not intend to belabor the safety concerns raised by MIOSHA, but Dr. Specht's failure to properly register the devices in accordance with Michigan law and ensure basic safety precautions is directly relevant to the quality and professionalism of his work and procedures, which in turn bear on the accuracy of the bone lead measurements that are so critical to Plaintiffs' claims. Dr. Specht's violations of Michigan law also are relevant to his credibility. As with the Thermo Fisher evidence, evidence that Dr. Specht cut corners in an effort to obtain bone lead measurements of Plaintiffs and other children in Flint bears on whether he might also have cut corners in validating the pXRF for use in children.

II. The Probative Value Of Evidence That Dr. Specht's pXRF Testing Is Experimental, Not Useful, Not Authorized, And Illegally Performed Is Not Substantially Outweighed By The Danger Of Undue Prejudice

Plaintiffs also are mistaken that evidence that Dr. Specht's pXRF testing is experimental, not useful, not authorized, and illegally performed is inadmissible under Rule 403, which states that a court "may exclude relevant evidence only if

'its probative value is substantially outweighed by a danger of . . . unfair prejudice.'" *United States v. Hazelwood*, 979 F.3d 398, 411-12 (6th Cir. 2020) (quoting Fed. R. Evid. 403).

The Sixth Circuit has made clear that the Rule 403 "[t]est is strongly weighted toward admission" of evidence. *United States v. Asher*, 910 F.3d 854, 860 (6th Cir. 2018). The "unfair prejudice" that Rule 403 is designed to prevent "mean[s] the undue tendency to suggest a decision based on improper considerations; it does not mean the damage to a [party's] case that results from legitimate probative force of the evidence." *United States v. Bilderbeck*, 163 F.3d 971, 978 (6th Cir. 1999). In fact, "'relevant evidence is inherently prejudicial.'" *United States v. Mills*, 704 F.2d 1553, 1559 (11th Cir. 1983) (quoting *United States v. McRae*, 593 F.2d 700, 707 (7th Cir. 1979)). Thus, the "major function [of Rule 403] is limited to excluding matter of scant or cumulative probative force, dragged in by the heels for the sake of its prejudicial effect." *Id*.

Evidence that Dr. Specht's pXRF testing is experimental, not useful, not authorized, and illegally performed is highly relevant to the jury's consideration of how much weight to afford the test results. And Dr. Specht will have the opportunity to rebut these challenges to his pXRF testing and defend his work. Plaintiffs will not be unduly prejudiced by these challenges to Dr. Specht's pXRF testing; nor will the challenges confuse the jury or waste time. To the extent

Plaintiffs are concerned that jurors might be confused into believing that they are being asked to decide whether Dr. Specht's pXRF testing is harmful to human health, that issue could easily be addressed through jury instructions, if necessary.

CONCLUSION

Plaintiffs' motion should be denied.

Respectfully submitted,

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Dated: December 28, 2021

CERTIFICATE OF SERVICE

I hereby certify that on December 28, 2021, I electronically filed this document with the Clerk of the Court using the ECF System, which will send notification to the ECF counsel of record.

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